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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,297	01/04/2002	Brigitte Chau Phan	BTI2 00103501(USP2)US	8429

7590

08/06/2004

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EXAMINER

LUM, LEON YUN BON

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 08/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/038,297	<b>Applicant(s)</b> PHAN ET AL.	
	<b>Examiner</b> Leon Y Lum	<b>Art Unit</b> 1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference character(s) mentioned in the description: "channel layer 302" (page 12, lines 28 and 31) are not in Figures 3A-3C. Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. In claim 1, line 1, the phrase "for use" is vague and indefinite. The specification does not define the term and it is not clear how the "solid phase" (line 1) is to be used in a "dual bead assay" (lines 1-2).

5. In claim 1, lines 3 and 5, the phrase "presence or absence of a cross-linking agent" is vague and indefinite. It is not clear whether the method as claimed would include the cross-linking agent or not include the cross-linking agent.

6. In claim 1, lines 5-6 and 7-8, the phrases "determining the percentage of probe bound covalently to the solid phase" and "calculating the percentage of probe bound covalently to the solid phase", respectively, are vague and confusing. The two phrases seem to recite the same limitation, wherein the terms "determining" (line 5) and "calculating" (line 7) are interpreted by the Examiner as synonyms of the same step, which is to elucidate the percentage of probe bound covalently to the solid phase. Therefore, it is unclear and confusing as to why the same step is disclosed twice in the same claim.

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7. The term "approximately" in claim 1 is a relative term which renders the claim indefinite. The term "approximately" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not known when "the solid phase is suitable for use in a dual bead assay" (lines 9-10) since it is unclear what percentage is required when "probe is bound covalently" (line 9).

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-2 and 5-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Sutton et al (US 5,147,777).

Sutton et al reference teaches a method of evaluating a solid phase for use in a dual bead assay, the method comprising selecting a test solid phase, binding a probe to the test solid phase in the presence of a cross-linking agent, determining the total amount of probe bound to the test solid phase in the presence of a cross-linking agent, determining the percentage of probe bound covalently to the solid phase, determining the amount of probe bound to the solid phase non-covalently, and calculating the

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percentage of probe bound covalently to the solid phase, wherein if no less than approximately 80% of the probe is bound covalently, the solid phase is suitable for use in a dual bead assay, by disclosing the preparation of several reagents having a radio-labeled protein attached to the polymeric particles with two different activating agents used to prepare the reagents (column 18, lines 55-61), wherein the polymeric particles include Poly(styrene-co-monomethacryloylpenta(oxyethylene) glutarate) and the protein was attached to the carboxy groups of the polymers using 1-(1-pyrrolidinyllcarbonyl)pyridinium chloride as activating agent (column 19, lines 1-14), wherein the protein is  $^3\text{H}$  labeled bovine gamma globulin (column 19, lines 15-16), wherein total  $^3\text{H}$  labeled bovine gamma globulin bound to the particles, the amount of  $^3\text{H}$  labeled bovine gamma globulin covalently bound to the particles and the covalent/total bound ratio are determined, wherein the results show that the reagents prepared acceptably bind antibody for use in immunoassays, and wherein Poly(styrene-co-monomethacryloylpenta(oxyethylene) glutarate) (Test C) had 90% of the protein covalently bound (column 19, lines 54-60 and Table I).

With regards to claim 2, Sutton et al reference teaches that the solid phase is a bead, by disclosing that the copolymers described herein are used in particulate form in order to prepare the reagents of this invention (column 8, lines 13-15).

With regards to claims 5-7, Sutton et al reference teaches that the probe is a nucleic acid and wherein the nucleic acid is double-stranded, and that the probe is a protein, by disclosing that the reagents have one or more biologically active substance covalently attached to the polymeric particles through the reactive carboxy groups on

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the outer surface of the particles (column 8, lines 19-22), wherein the biologically active substance can be nucleic acids, wherein the nucleic acid is double-stranded (column 8, lines 36-54, particularly lines 49-50), and wherein the biologically active substance can be proteins (column 8, lines 36-54, particularly lines 40-42).

With regards to claim 8, Sutton et al reference teaches that the probe further comprises a linker, by disclosing a tetraethylene glycol amine linker attached to  $\beta$ -globin DNA (column 21, lines 9-25).

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sutton et al (US 5,147,777) in view of Ullman et al (US 6,103,537).

Sutton et al reference has been disclosed above and additionally teaches that the copolymers produced are latex particles which facilitate attachment of proteins or other biological compounds (column 5, lines 9-11), but fails to disclose that the bead is a magnetic bead.

Ullman et al reference teaches magnetic latex beads, preactivated to covalently bind protein, in order to capture receptors of interest, wherein detection is facilitated through immobilization of the magnetic beads by application of a magnetic field (column 26, lines 4-61, specifically lines 4-11 and lines 48-51).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Sutton et al, with magnetic latex beads, preactivated to covalently bind protein, as taught by Ullman et al, in order to capture receptors of

interest, wherein detection is facilitated through immobilization of the magnetic beads by application of a magnetic field. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in using the magnetic latex beads, as taught by Ullman et al, in the method of Sutton et al, since Sutton et al teach latex particles with covalently bonded proteins for immunoassays, and the magnetic latex beads can also covalently bind proteins. Furthermore, magnetic latex beads and colored latex beads are well known in the art as being functionally equivalent.

14. Claims 4 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutton et al (US 5,147,777) in view of Gustafson et al (US 5,413,939).

Sutton et al reference has been disclosed above and additionally teaches that the copolymers produced are latex particles which facilitate attachment of proteins or other biological compounds (column 5, lines 9-11), but fails to disclose that the solid phase is a surface on a biodisc or that the test solid phase is attached to a biodisc.

Gustafson et al reference teaches particles such as latex that are coupled to a binding pair (column 5, lines 53-57), wherein the analyte to be detected will be a member of a naturally-occurring binding pair (column 4, lines 3-9), and wherein the presence of the analyte in the sample will be measured by detecting specific binding between the analyte and an anti-analyte covalently bound to a surface on a solid phase support, usually a disk (column 4, lines 21-25), in order to measure analytes using a solid-phase binding assay system (column 1, lines 7-8), wherein the interactions include protein or DNA binding reagents (column 5, lines 11-52, particularly lines 28-31).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Sutton et al, with particles such as latex that are coupled to a binding pair, wherein the analyte to be detected will be a member of a naturally-occurring binding pair, and wherein the presence of the analyte in the sample will be measured by detecting specific binding between the analyte and an anti-analyte covalently bound to a surface on a solid phase support, usually a disk, as taught by Gustafson et al, in order to measure analytes using a solid-phase binding assay system, wherein the interactions include protein or DNA binding reagents. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in using the latex particles on a solid phase support disk, as taught by Gustafson, in the method of Sutton et al, since Sutton et al teach latex particles with covalently bonded proteins for immunoassays, and the latex particles on a solid phase support disk are also covalently bound and can also specifically bind proteins for analyte detection.

15. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sutton et al (US 5,147,777) in view of Heinonen et al (US 5,912,342).

Sutton et al reference has been disclosed above and additionally teaches that the copolymers produced are latex particles which facilitate attachment of proteins or other biological compounds (column 5, lines 9-11), but fails to disclose that the linker is at least one polyethylene glycol moiety.

Heinonen et al reference teaches that polyethylene glycol can be grafted onto materials such as polystyrene, in order to react with various types of organic molecules

to form covalent linkage and to bind covalently chemical compounds (column 3, lines 63-67 and column 4, lines 1-4).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Sutton et al, with polyethylene glycol that can be grafted onto materials such as polystyrene, as taught by Heinonen et al, in order to react with various types of organic molecules to form covalent linkage and to bind covalently chemical compounds. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in using the polyethylene glycol, as taught by Heinonen et al, in the method of Sutton et al, since Sutton et al teach polystyrene copolymers that have covalently bonded proteins for immunoassays, and the polyethylene glycol can be grafted on polystyrene for covalent binding of molecules.

### ***Double Patenting***

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/086941. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons:

Both the instant application and copending application claim a method of evaluating a solid phase for use in a dual bead assay, the method comprising selecting a test solid phase, binding a probe to test solid phase in the presence or absence of a cross-linking agent, determining the total amount of probe bound to the test solid phase in the presence or absence of a cross-linking agent, determining the percentage of probe bound covalently to the solid phase, determining the amount of probe bound to the solid phase non-covalently, and calculating the percentage of probe bound covalently to the solid phase, wherein if no less than a predetermined minimum threshold of the probe is bound covalently, the solid phase is suitable for use in a dual bead assay.

Since the phrase "wherein if no less than approximately 80% of the probe is bound covalently" (lines 8-9) in the instant application is narrower than the phrase "wherein if no less than a pre-determined minimum threshold of the probes is bound covalently" (lines 11-12) of the copending application, the claims of the copending application anticipates those of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

18. No claims are allowed.

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Danielson et al (US 5,155,166) teach protein covalently bound to particles and obtaining a covalent/total bound ratio for use in immunoassays.

Scensny et al (US 5,266,500) teach methods of attaching compounds to polymeric particles and obtaining a covalent/total bound ratio.

Nustad, K. et al. (Agents Action Suppl., 1982) teach immobilization of antibodies to a solid phase through covalent coupling.

von Klitzing, L. et al. (IAEA-SM-259/63) teach comparisons between adsorption and covalent coupling of proteins to different types of solid phases.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on 8:00am-5:00pm.

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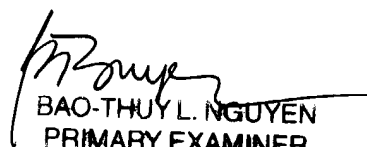
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LYL



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